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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,993	02/17/2004	James D. Lewis JR.	HT-5755 DIV	1329

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BAXTER HEALTHCARE CORPORATION
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EXAMINER

MOHANDESI, JILA M

ART UNIT	PAPER NUMBER
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3728

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/779,993	Applicant(s) LEWIS ET AL.	
	Examiner Jila M. Mohandesi	Art Unit 3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 22-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/28/2006 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. (4,692,361). Johnson '361 discloses a container for holding products to be maintained and removed under sterile conditions, comprising: a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall, permanent seals about a periphery of the first and second walls, the seals joining an interior portion of the opposing first and second walls and creating a fluid-tight chamber within the cavity of the container and a fitment (see column 6, lines 57-61). See Figures 1 and 2 embodiments and column 1, lines 11-21. Johnson '361 discloses that the flexible containers are utilized in medical industry for containing, inter alias,

parenteral solutions, dialysis solutions, frozen drugs and plasma. Cruise '975 discloses that it is desirable to store albumin (at least about 20% albumin) in separate containers and flexible bags (146), see Figure 7B embodiment. Regarding the actual product or composition (concentration of at least 20% albumin), the actual composition is merely a matter of user preference and entirely obvious to use whatever composition as desired. The flexible polymeric bag of Johnston '361 is capable of holding concentration of at least 20% albumin. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to store albumin concentrations in the flexible polymeric bag of Johnston '361, since the bag of Johnston '361 is suitable and utilized in the medical industry for containing, inter alia, parenteral solutions, dialysis solutions, frozen drugs and plasma (which contains albumin).

With respect to claims 11 and 12, see Figure 1 embodiment and column 3, lines 37-49.

The limitation under Official Notice is now taken as admitted prior art, therefore, with respect to claim 2, it would have been obvious to one of ordinary skill in the art at the time the invention was made in view of the admitted prior art to mix albumin with sterilized water and stabilizers.

4. Claims 8, 13 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Johnston '361 as applied to claims 1 and 3 above, and further in view of Bacehowski et al. (4,910,147). Johnston '361 as described above discloses all the limitations of the claims except for the flexible bag further comprising an aperture adjacent an edge opposing the fitment. Bacehowski '147 discloses a flexible bag with

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an aperture adjacent an edge opposing the fitment to facilitate hanging of the flexible bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an aperture adjacent an edge opposing the fitment of the flexible bag of Johnston '361 as taught by Bacehowski '147 to facilitate hanging of the flexible bag.

5. Claims 9-10 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston '361 as applied to claims 1, 3 and 5 above, and further in view of Bell et al. (4,936,456). Johnston '361 as modified above discloses all the limitation of the claims except for it is silent about the type of seal being used. Bell '456 discloses that chevron seals can be used instead of linear seals for closing the edges of a flexible bag. As a result of the chevron seal construction, relatively log tabs are formed to facilitate opening through stripping of the gussets from the bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide chevron seals in the flexible bag of Johnston '361 as taught by Bell '456 to facilitate opening through stripping of the gussets from the bag.

Response to Arguments

6. Applicant's arguments with respect to claims 1-13 and 22-27 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

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USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

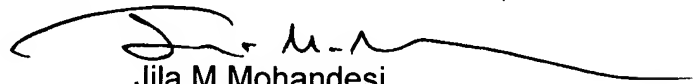
In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jila M. Mohandesi whose telephone number is (571) 272-4558. The examiner can normally be reached on Monday-Friday 7:30-4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jila M Mohandesi
Primary Examiner
Art Unit 3728

JMM
February 07, 2007